

AMENDED IN ASSEMBLY APRIL 11, 1996

CALIFORNIA LEGISLATURE—1995–96 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2915**

**Introduced by Assembly Member Friedman**

February 22, 1996

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An act to add Article 1 (commencing with Section 104145) to Chapter 2 of Part 1 of Division 103 of the Health and Safety Code, and to repeal Section 9 of Chapter 661 of the Statutes of 1993, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 2915, as amended, Friedman. Breast cancer research.

Existing law, in an uncodified statute (Sec. 9, Ch. 661, Stats. 1993), creates a Breast Cancer Research Program and requests the University of California to administer the program as a comprehensive grant and contract program to support research efforts into the cause, cure, treatment, earlier detection, and prevention of breast cancer. It states intent of the Legislature that the University of California establish a Breast Cancer Research Council with specified membership and duties.

This bill would repeal these uncodified provisions of law and would reenact them, as amended, in a codified statute. It would request the University of California and the council to work in close collaboration with the Breast Cancer Early Detection Program, revise provisions governing membership in the council and impose funding eligibility limitations on council members, as specified, and expand the groups of

persons who may be recruited for participation in a peer review panel, among other things.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. Article 1 (commencing with Section 104145) is added to Chapter 2 of Part 1 of Division 103 of the Health and Safety Code, to read:

Article 1. The Breast Cancer Research Program

104145. (a) The Legislature hereby requests the University of California to establish and administer the Breast Cancer Research Program, which is created by this act, as a comprehensive grant and contract program to support research efforts into the cause, cure, treatment, earlier detection, and prevention of breast cancer. It is the intent of the Legislature that this program incorporate the principles and organizational elements specified in this act, including, but not limited to, a research program office with a director and other necessary staff, a Breast Cancer Research Council, and research review panels.

(b) For the purposes of this section:

(1) “Breast cancer research” includes, but is not limited to, research in the fields of biomedical science and engineering, the social, economic and behavioral sciences, epidemiology, technology development and translation, and public health.

(2) “Council” means the Breast Cancer Research Council.

(3) “Grantee” means any qualifying public, private, or nonprofit agency or individual, including, but not limited to, colleges, universities, hospitals, laboratories, research institutions, local health departments, voluntary health agencies, health maintenance organizations, corporations, students, fellows, entrepreneurs, and individuals conducting research in California.

1 (4) “Program” means the Breast Cancer Research  
2 Program.

3 (5) “University” means the University of California.

4 (c) It is the intent of the Legislature that this program  
5 be administered pursuant to the following principles:

6 (1) The university is requested to work in close  
7 collaboration with the council and seek the consent of the  
8 council before taking an action different from the action  
9 recommended by the council.

10 (2) The council shall develop the strategic objectives  
11 and priorities of the program, actively participate in the  
12 overall management of the program, and make final  
13 recommendations on which research grants should be  
14 funded based on the research priorities established for  
15 the program and the technical merits of the proposals as  
16 determined by peer review panels.

17 (3) The program shall fund innovative and creative  
18 research, with a special emphasis on research that  
19 complements, rather than duplicates, the research  
20 funded by the federal government and other entities.

21 (4) The university should and the council shall work in  
22 close collaboration with the Breast Cancer Early  
23 Detection Program.

24 (5) All research funds shall be awarded on the basis of  
25 the research priorities established for the program and  
26 the scientific merit of the proposed research, as  
27 determined by an open, competitive peer review process  
28 that ensures objectivity, consistency, and high quality. All  
29 investigators, regardless of affiliation, shall have equal  
30 access and opportunity to compete for program funds.

31 (6) The peer review process for the selection of  
32 research grants awarded under this program shall be  
33 generally modeled on that used by the National Institutes  
34 of Health in its grantmaking process.

35 (7) An awardee shall be awarded grants for the full  
36 cost, both direct and indirect, of conducting the  
37 sponsored research consistent with those federal  
38 guidelines governing all federal research grants and  
39 contracts. All intellectual property assets developed

1 under this program shall be treated in accordance with  
2 state and federal law.

3 (d) It is the intent of the Legislature that the  
4 university, as lead agency, do all of the following:

5 (1) Establish the Breast Cancer Research Council in  
6 accordance with the following:

7 (A) The council shall consist of at least 13 and no more  
8 than 15 members representing a range of expertise and  
9 experience, appointed by the President of the University  
10 of California from nominations solicited from and  
11 submitted by relevant organizations, as follows:

12 (i) Four members from breast cancer survivor and  
13 breast cancer-related advocacy groups, including, but not  
14 limited to, the California Breast Cancer Organizations  
15 (CABCO).

16 (ii) Four members drawn from the ranks of scientists  
17 or clinicians, including one from an independent  
18 research university in California. The scientists shall have  
19 expertise covering the various fields of scientific  
20 endeavor, including, but not limited to, the fields of  
21 biomedical research and engineering, social, economic,  
22 and behavioral research, epidemiology, and public  
23 health.

24 (iii) Two members from nonprofit health  
25 organizations with a commitment to breast cancer  
26 research and control.

27 (iv) One member who is a practicing breast cancer  
28 medical specialist.

29 (v) Two members from private industry with a  
30 demonstrated commitment to breast cancer research and  
31 control, including, but not limited to, entrepreneurs, or  
32 persons from the science or high technology industry or  
33 persons from the health care sector.

34 (vi) One ex officio, nonvoting member from the  
35 Breast Cancer Early Detection Program.

36 (B) If the president appoints more than 13 members,  
37 it is the intent of the Legislature that the proportional  
38 representation remain substantially the same as set forth  
39 in subparagraph (A).



(C) Members shall serve without compensation, but may receive reimbursement for travel and other necessary expenses actually incurred in the performance of their official duties. Any member of the Breast Cancer Research Council shall be ineligible to receive funding for breast cancer research from the Breast Cancer Research Program during his or her term of service on the council.

(D) Membership shall be staggered in such a way as to maintain a full council while ensuring a reasonable degree of continuity of expertise and consistency of direction.

(2) Provide overall coordination of the program.

(3) Provide staff assistance to the program and council.

(4) Develop administrative procedures relative to the solicitation, review, and awarding of grants to ensure an impartial, high quality peer review system.

(5) Recruit and supervise research review panels. The membership of these panels shall vary depending on the subject matter of *the* proposals and *the* review requirements, and shall draw on the most qualified individuals. The work of the review panels shall be administered pursuant to policies and procedures established for the implementation of the program. In order to avoid conflicts of interest and to ensure access to qualified reviewers, it is the intent of the Legislature that the university utilize reviewers from outside the state *unless reviewers with expertise in particular research grant proposals are only available within the state*. When serving on review panels, institutions, corporations, or individuals who have submitted grant applications for funding by this program shall be governed by conflict-of-interest provisions consistent with the National Institutes of Health Manual (Chapter 4510 (item h)), and any applicable conflict-of-interest provisions in state law.

(6) Provide for periodic program evaluation to ensure that research funded is consistent with program goals.

(7) Maintain a system of financial reporting and accountability.

1 (8) Provide for the systematic dissemination of  
2 research results to the public and the health care  
3 community, and provide for a mechanism to disseminate  
4 the most current research findings in the areas of cause,  
5 treatment, cure, earlier detection, and prevention of  
6 breast cancer, in order that these findings may be applied  
7 to the planning, implementation, and evaluation of the  
8 breast cancer-related programs of the State Department  
9 of Health Services, including the Breast Cancer Early  
10 Detection Program authorized by this act.

11 (9) Develop policies and procedures to facilitate the  
12 translation of research results into commercial, alternate  
13 technological, and other applications wherever  
14 appropriate and consistent with state and federal law.

15 (10) Transmit annually on or before each December  
16 31, a report to the Legislature on grants made, grants in  
17 progress, program accomplishments, and future program  
18 directions. Each report shall include, but not be limited  
19 to, the following information:

20 (A) The number and dollar amounts of research  
21 grants, including the amount allocated to indirect costs.

22 (B) The subject of research grants.

23 (C) The relationship between federal and state  
24 funding for breast cancer research.

25 (D) The relationship between each project and the  
26 overall strategy of the research program.

27 (E) A summary of research findings including  
28 discussion of promising new areas.

29 (F) The institutions and campuses receiving grant  
30 awards.

31 (e) It is the intent of the Legislature that no more than  
32 5 percent of the allocation to the university be used for  
33 the purposes of administration of this program.

34 (f) It is the intent of the Legislature that the  
35 responsibilities of the council shall include, but not be  
36 limited to, the following:

37 (1) Development and review of the strategic  
38 objectives and research priorities of the program.

39 (2) Delineation of resource allocation across the  
40 various priorities established for the program.

1 (3) Participation in periodic program and financial  
2 review, including the report transmitted pursuant to  
3 paragraph (10) of subdivision (d).

4 (4) Development and review of guidelines to ensure  
5 fairness, neutrality, and adherence to the principles of  
6 merit and quality in the conduct of the program.

7 (5) Development of appropriate linkages to  
8 nonacademic entities, including, but not limited to,  
9 voluntary organizations, health care delivery systems,  
10 industry, government agencies, research entrepreneurs,  
11 and public officials.

12 (6) Development and review of criteria and standards  
13 for granting awards.

14 (7) Oversight and review of the request for  
15 applications (RFA).

16 (8) Review of research review panel reports and  
17 recommendations for grant awards.

18 (9) Making of final recommendations on which grants  
19 are to be awarded.

20 (10) Development and review of oversight  
21 mechanisms for the dissemination of research results.

22 (11) Development and review of policies and liaison  
23 programs to facilitate the translation of research results  
24 into commercial, alternate technological, or other  
25 applications wherever appropriate.

26 (12) Establishment of its own internal rules of  
27 operation.

28 (13) Participation in the identification and  
29 recruitment of breast cancer advocates and survivors,  
30 clinicians, scientists, and persons from the science, high  
31 technology, or health care sector with relevant expertise  
32 for possible participation in a peer review panel. The  
33 council may propose to assign a member of the council to  
34 sit as a nonvoting member of the peer review panels.

35 SEC. 2. Section 9 of Chapter 661 of the Statutes of 1993  
36 is repealed.

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